



Next Steps for Biorisk Assessment: Turning Methodologies into Tools

International Biological Threat Reduction
Sandia National Laboratories
Albuquerque, NM USA

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www.biosecurity.sandia.gov

SAND No. 2008-1141P
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.



New Tools Under Development

- **Biosafety Wiki**
 - Goal: centralized resource for data needed in biorisk assessment
- **Biosecurity Risk Assessment Methodology (BioRAM)**
 - Goal: Develop a tool to help community conduct biosecurity risk assessments
- **Biosafety Risk Assessment Methodology (BiosafetyRAM)**
 - Goal: Develop a tool to help community conduct biosafety risk assessments





THE WIKIPEDIA OF BIOSAFETY

www.BiosafetyRiskAssessment.org

BIOSAFETY
Risk Assessment

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SAND 2007-5956P

BIOSAFETY RISK ASSESSMENT WIKI



- The Biosafety Risk Assessment Wiki website is designed to help assess the biosafety risk of working with specific biological agents by collaborating with colleagues and other experts in the field
- Risk assessment is the foundation of a good biosafety program
 - No widely accepted set of qualitative or quantitative tools to help biosafety professionals conduct assessments
 - Critical information that is pertinent to biosafety risk assessments is often hard to find and is not consolidated
- The Biosafety Risk Assessment Wiki aims to assemble this information in a coherent fashion and present it alongside contributions by subject matter experts
- Successful risk management can only be achieved with a thorough understanding of all hazards and risks involved in laboratory work



WHAT IS A WIKI?

- A wiki is a website for facilitating collaboration among peers to produce a consensus text
 - Wikis also provide a central point for sharing information and discussing ideas through text, links, and references
- The Biosafety Risk Assessment Wiki is a repository of risk assessment data, publications, and links for the biosafety community.
 - Contributors are interested professionals and experts in the biosafety field
 - The site is available to the public, but to ensure that the information on the wiki is as accurate and reliable as possible, only those with biosafety expertise will be given editing privileges
 - The site is managed and content controlled by the International Biological Threat Reduction program at Sandia National Laboratories

CONTENT



- **Agent Hazards**
 - Fact-based information regarding a specific agent's risk that contribute to the probability and consequence of exposure
 - Bacteria
 - Viruses
 - Proteins
 - Rickettsia
 - Fungi
 - Parasites
- **Laboratory Procedure Hazards and Hazard Mitigation Measures**
 - Discussion-oriented sections to include different laboratory procedure hazards and mitigation measures
- **Agent and Laboratory information is outlined based upon a template designed by a biosafety experts panel**
 - This template follows a biosafety risk assessment methodology currently in development



AGENT HAZARDS



BIOSAFETY RISK ASSESSMENT - MICROBIOLOGICAL EXPERT

Home | Search | Favorites | History | Back | Forward | Stop | Reload | Print | Home | Search | Favorites | History | Back | Forward | Stop | Reload | Print | Home

Address: [http://www.biosafetyrisk.com/agent_hazards.html](#)

Google

article | **discuss** | edit | title

Agent Hazards

Discuss this main page

This page by an agent-specific discussion to support accurate safety assessments with an agent. Some new agent-related information can be hard to find from more general discussion of the risks which can vary depending on aspects of the human and animal exposure in the region, unique human exposure patterns, and the existing knowledge of the agent's pathogenesis. However, research is more likely to be done to protect human and environmental health. The agent we have already used the last a while ago, will be to do in an agent-specific discussion of the agent's pathogenesis.

Agent Groups

| | | |
|----------|-----------|--------------|
| Bacteria | Fungal | Viruses |
| Protozoa | Parasites | Biochemicals |

Definitions

Select agent table

- Fungal Fungal Community Guidelines
- NH Guidelines on Recombinant DNA
- Canadian Laboratory Biosafety Guidelines
- WHO - Microbiology, Biotechnology and Laboratory Guidelines
- Public Health Agency of Canada - Health Organization - A Guide to the Use of Biosafety Cabinets

BIOSAFETY RISK ASSESSMENT MICROBIAL INFECTION EXPLOITER

Home Search Favorites Downloads Tools

Address: .../clostridium-tetani.html

Google

article | **discuss** | edit | info

Clostridium tetani

back to table of contents

Contents:

- 1 Introduction
- 2 Agent Info
- 3 Pathogen Types
- 4 Links
- 5 Agent Information
- 6 Discussion
- 7 Related External Resources
- 8 Citations

Background [edit](#)

Cause of tetanus (lockjaw), a severe, painful, and potentially fatal disease. The organism is a soil-dwelling, anaerobic, gram-negative bacillus that produces an extremely potent neurotoxin.

Agent Criteria [edit](#)

Infectious Dose: 10⁶ to 10⁸ spores

Latency:

Colonization Potential:

Stability: Spores are resistant to many disinfectants and can survive for up to 10 years in soil. The vegetative form is highly sensitive to heat and is killed by autoclaving.

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LABORATORY PROCEDURE HAZARDS



HAZARD MITIGATION MEASURES



BIOSAFETY RISK ASSESSMENT: MICROBIAL INCUBATION EXPOSURE

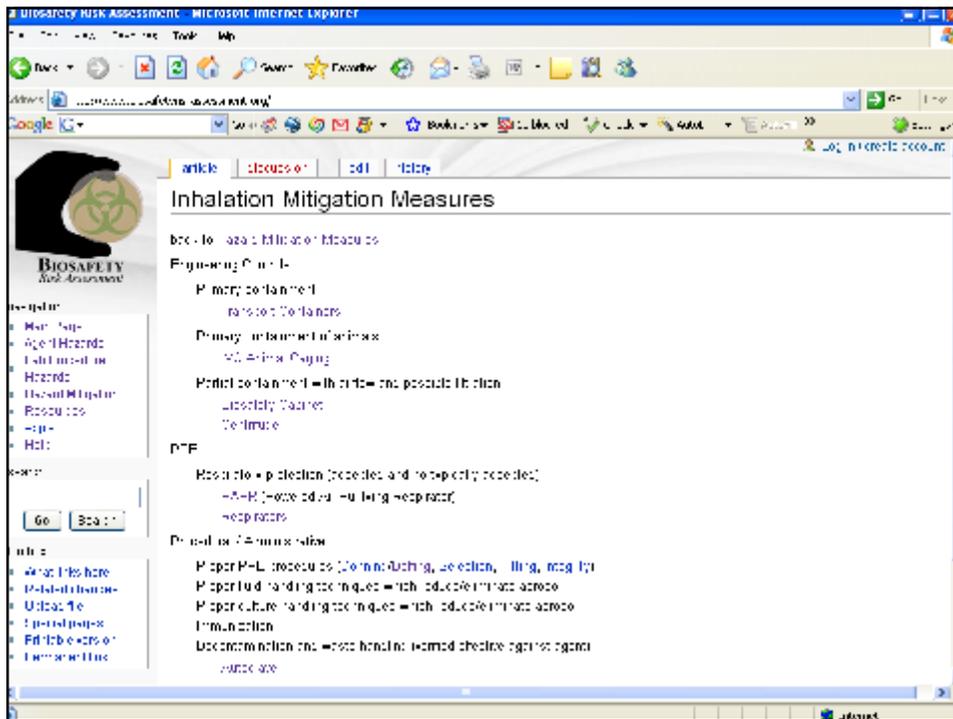
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Hazard Mitigation Measures

Microbes Wiki main page

This page lists the most effective methods of mitigating risk in the secondary, high containment area use of safety equipment, safety procedures and facility design. It is important to recognize the methods and barriers that will mitigate hazards in your laboratory and assess the residual risk assessments and the mitigation measures of your facility. This list is not an all-inclusive, primary concern is to list and secondary to determine the barriers of need to be in place to ensure a safe and sound environment in the laboratory. Mitigation measures are listed in order of increasing risk.

- Inhalation**
Measures that may reduce the risk of entering and breathing in and/or contact with the pathogen existing in your facility, including:
- Inoculation**
Measures that may reduce the possibility of microbes in the laboratory coming into contact with the CLS.
- Percutaneous**
Measures that may reduce the risk of puncturing or cutting the skin.
- Contact**
Measures that may reduce the risk of contact with the skin or clothing.



CONCLUSION



- Goal: To become a valuable risk assessment resource for the biosafety community
- This site is still only a skeleton
 - It will require expert input before it can truly become **the *Wikipedia of Biosafety***
- Thanks to the 2nd International Biorisk Management Workshop at the Canadian Science Center for Human and Animal Health in Winnipeg

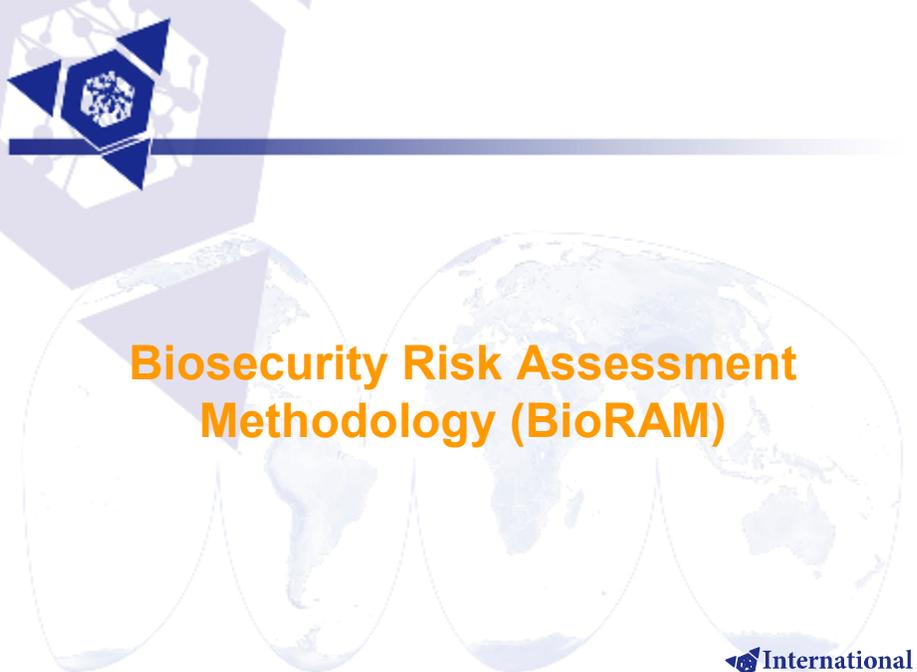


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THE WIKIPEDIA OF BIOSAFETY

www.BiosafetyRiskAssessment.org

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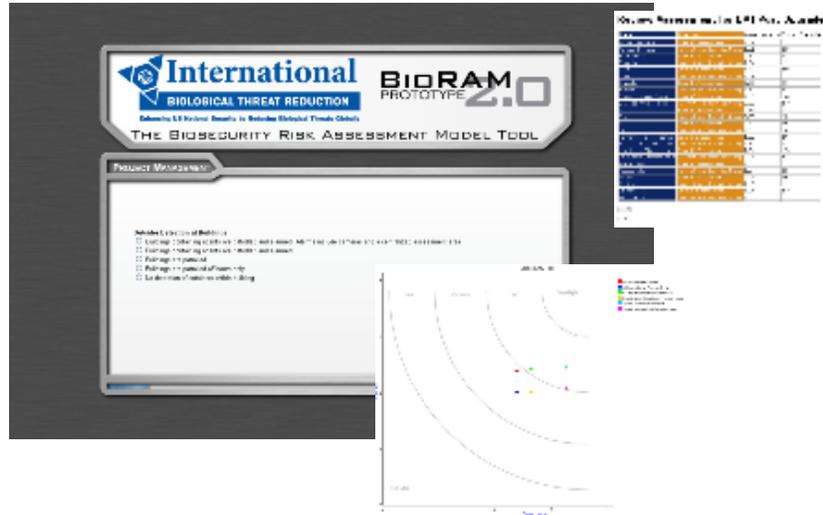


Biosecurity Risk Assessment Methodology (BioRAM)



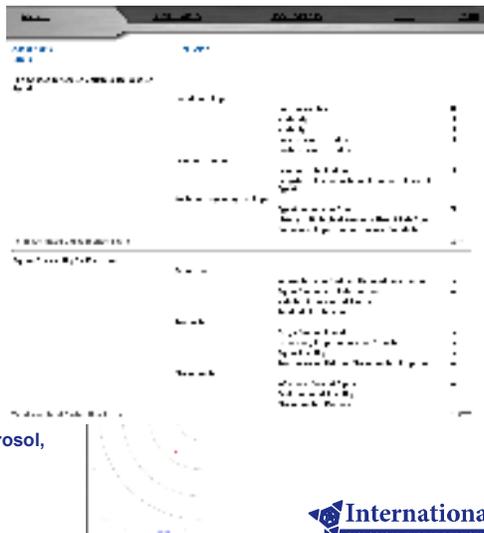


BioRAM 2.0 Software Tool



Asset Assessment

- **Assess value of the agents from an adversary's perspective**
 - **Consequences**
 - Population
 - Transmissibility
 - Mortality
 - Morbidity
 - Economic
 - Psychological
 - **Task Complexity**
 - Acquisition
 - Natural
 - Laboratory
 - Synthetic biology
 - Production
 - R&D
 - Covert production
 - Ease of storage
 - Dissemination
 - Route of infection (e.g. aerosol, ingestion)
 - Environmental hardiness





Threat Assessment

- **Adversary Classes**

- Terrorist
- Extremist
- Criminal

- **Insiders**

- Insiders have authorized access to the facility, agents, and/or restricted information
- Distinguish Insiders by level of authorized access

- Site
- Building
- Asset

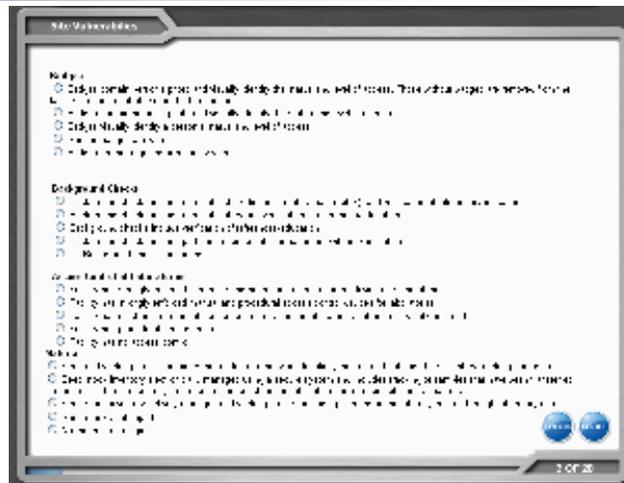
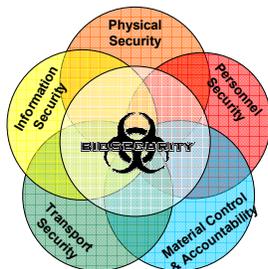
- **Outsiders**

- Outsiders have no authorized access
- To assess, interview local law enforcement, site security, and intelligence community



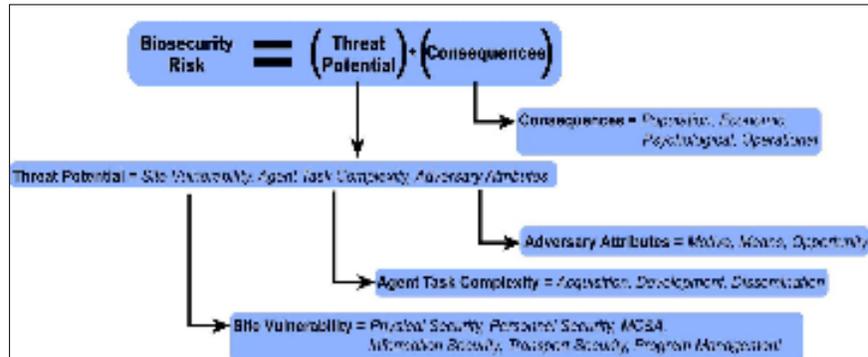
Vulnerability Assessment

- Evaluate the effectiveness of each of the components of the existing laboratory biosecurity system





Biosecurity Risk Assessment Methodology



Pilot Studies of Biosecurity Risk Assessment Methodology in Japan

- **Test facilities**
 - Reference laboratories
 - Regional public health laboratory
 - Hospital laboratory
 - University laboratory (one division)
- **Respondents**
 - Senior management vs. Technical chief
 - Different departments in same facility



BioRAM Next Steps

- **Improvements to methodology – Summer 2009**
 - Based on lessons learned by
 - Using tool and from developing Biosafety RAM
- **Create stand-alone CD-ROM version of tool – 2010**
- **In partnership with Japanese National Institute of Infectious Diseases**



Project Origins: 2nd Biorisk Management Workshop, 2007

- **Held at the Canadian Science Centre for Human and Animal Health**
 - Organized by the National Microbiology Laboratory's Office of Biorisk Management (part of the Public Health Agency of Canada)
 - Winnipeg, Manitoba, February 2007
- **Participants charged with discussing and, if possible, developing a common approach to biological risk assessment for the laboratory**
- **From the workshop report: "The current lack of a clearly quantifiable processes makes biological risk assessment a predominantly qualitative approach and, as such, potentially highly subjective, variable, and inconsistent."**
 - Next steps include "the establishment of a comprehensive toolkit for biological risk assessment"
- **Following the workshop, Sandia sought and received three years of internal R&D funding to develop a quantitative biosafety risk assessment methodology and software tool**
 - Biosafety RAM
- **"Biological Risk Assessment in the Laboratory: Report of the Second Biorisk Management Workshop," *Applied Biosafety*, Vol. 13, No. 3, 2008**



Collaborative Effort Required to Advance the Project

- **Project is a collaborative effort among ABSA, the Canadian Science Centre for Human and Animal Health, and Sandia National Laboratories**
 - The biosafety community and the microbiology community are key contributors
- **Upon completion, the methodology will be made publicly available**
- **The prototype software tool will be tested and reviewed by members of the biosafety and microbiology community**
- **The production version of the software tool will be made publicly available**



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3rd Biorisk Management Workshop, 2008

- **Held at the Canadian Science Centre for Human and Animal Health**
 - Organized by the National Microbiology Laboratory's Office of Biorisk Management (part of the Public Health Agency of Canada)
 - Winnipeg, Manitoba, March 2008
- **International participants charged with outlining the criteria and developing risk definitions for the Biosafety RAM project**
 - 13 participants from the US, Canada, Japan, and Singapore



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Project Goals and Milestones

| Goal | Milestone | Completion Date |
|--|---|-----------------|
| Outline Methodology | Review method with SMEs | 03/2008 |
| Establish criteria | Agent hazard criteria | 05/2008 |
| | Laboratory hazard criteria | 05/2008 |
| | Hazard mitigation criteria | 05/2008 |
| Determine relative importance among criteria | Determine relationship among the criteria | 06/2008 |
| | Weight the criteria | 10/2008 |
| Create prototype model | Create prototype model | 11/2008 |
| | Test model with SMEs | 4/2009 |
| | Present overall methodology/model for peer review | 05/2009 |
| Develop software tool | Develop alpha software tool to implement model | 09/2009 |
| | Validate software tool | 12/2009 |
| | Finalize software tool and implement revisions | 04/2010 |
| Final report and tool | | 09/2010 |

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Expected Project Results

- **Deliver a quantitative, repeatable biosafety risk assessment methodology and associated software tool**
- **Promote the use of the tool throughout the international bioscience community**
 - Especially in the many new high containment laboratories around the globe
 - Increase standardization of biological safety risk assessments
- **Improve understanding that there is no such thing as zero biosafety risk in biocontainment facilities**
 - Help to articulate and communicate the real risks at these facilities -- to users, managers, and the public
- **Develop a methodology that is flexible and allows for modification**
 - Biosafety RAM tool will be based upon this methodology
- **Strengthen the practice of biosafety and improve the reliability of infectious disease research, outbreak response, and diagnostics globally**





Biosafety Risk Assessment Methodology (RAM)

- **This methodology will be the basis for a systematic, standardized tool that includes:**
 - Accepted criteria for assessing the risk
 - A “scoring system” for evaluating the situation against the criteria
 - Relative weights for the criteria
 - An equation that combines the criteria scores and the relative weights to produce a measure of risk



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BIOLOGICAL THREAT REDUCTION



Biosafety Risk Definitions

Risk = f (Likelihood, Consequence)

- **Likelihood**
 - Likelihood of infection based upon agent properties
 - Likelihood of exposure based upon laboratory hazards
- **Consequences are based upon agent properties**
- **Risk calculated independently for**
 - Individuals performing direct manipulation upon agent
 - Individuals also working in the laboratory
 - Individuals with no laboratory access but also in the facility
 - The human community outside the laboratory
 - The animal community outside the laboratory (domestic, agricultural, and wildlife)
 - The risk of secondary transmission to both the human and animal community



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Project Scope

- **Results are agent/laboratory procedure based**
 - Assessing multiple research protocols in one assessment is feasible, but will blend the results, making management more difficult
- **Hazards beyond the defined laboratory activity are not specifically addressed, but information regarding those risks can be included**
 - E.g. if working with human blood, the risk assessment does not automatically include all potential blood and body fluid risks; however, those agents can be added into the assessment tool
 - E.g. if working with animals, the risks of animal bites/scratches beyond the agents identified in the assessment are not included; however, those additional risks can be added into the assessment tool



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Summary and Next Steps

- **Members of the biosafety community and the microbiology community vetted and weighted the criteria**
 - Reno Oct 23-24, 2008
 - Winnipeg April 13 – 17, 2009
- **Prototype model to be tested during the fall of 2009**
 - Finalized model and tool to be released in the fall of 2010
- **Preliminary methodology reports and trainings to be released prior to model prototype and finalization**
- **Community feedback and support are key!**
 - This is a community risk assessment methodology and tool



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